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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/754,998	01/04/2001	Ernst H. Rinderknecht	P0941CID1C1	4682
9157	7590	02/05/2004	EXAMINER	
GENENTECH, INC.			HELMS, LARRY RONALD	
1 DNA WAY			ART UNIT	
SOUTH SAN FRANCISCO, CA 94080			PAPER NUMBER	
			1642	

DATE MAILED: 02/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/754,998

Applicant(s)

RINDERKNECHT ET AL

Examiner

Larry R. Helms

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 28-30 is/are pending in the application.
- 4a) Of the above claim(s) 29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 28 and 30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

1. Claims 19-27 and 31 have been canceled.

Claims 28-30 have been amended.

2. Claim 29 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention. Applicant timely traversed the restriction (election) requirement in Paper No. 11.

3. Claims 28 and 30 are under examination. The claims are being examined to the extent the species is an antibody to P185 HER2.

4. The text of those sections of Title 35 U.S.C. code not included in this office action can be found in a prior Office Action.

Rejections Withdrawn

5. The rejection of claims 27-28 under 35 U.S.C. 103(a) as being unpatentable over Carter et al (U. S. Patent 6,054,297, filed 5/95 with priority as a CON to 8/92) and further in view of Morimoto et al (J. Biochem. Biophys. Methods 24:107-17, 1992, IDS #4.5) is withdrawn in view of the amendments to the claims.

6. The rejection of claims 27-28 under 35 U.S.C. 103(a) as being unpatentable over Hudziak et al (WO 89/06692, published 7/89) and further in view of Morimoto et al (J. Biochem. Biophys. Methods 24:107-17, 1992, IDS #4.5) is withdrawn in view of the amendments to the claims.

7. The rejection of Claim 27 under 35 U.S.C. 102(b) as being anticipated by Morimoto et al (J. Biochem. Biophys. Methods 24:107-17, 1992, IDS #4.5) is withdrawn in view of the amendment to the claim.

Response to Arguments

8. The rejection of claim 30 under 35 U.S.C. 102(b) as being anticipated by Neblock et al (Bioconjugate Chem. 3:126-131, 1992, IDS #4 ½) is maintained.

The response filed 11/17/03 and 10/14/03 have been carefully considered but is deemed not to be persuasive. The response states that Neblock et al contains a thioether-cross linked bispecific F(ab')₂ present at approximately 93%, not a composition as in Applicants' claim 30 comprising a correctly disulfide linked antibody fragment where as Applicants disclose on page 9 of the specification, all cysteine residues in the antibody are covalently associated as disulfide bonds and these disulfide associations correspond to the disulfide associations of the native immunoglobulin (see page 6 of response). In response to this argument, page 9 states that "correctly disulfide linked is meant that all cysteine residues in the antibody are covalently associated as disulfide bonds and these disulfide associations correspond to the disulfide associations of the native immunoglobulin". Thus, the molecule of Neblock et al meets the limitation because Neblock teach compositions comprising phosphate buffer and a bispecific F(ab')₂ and a Fab' molecule. Because the Fab' is not correctly disulfide linked (it does not have a correct disulfide bond to another Fab' fragment) and

the H-L chains in some molecules were reduced, therefore the composition comprises incorrectly disulfide molecules.

9. The rejection of claims 28 and 30 under 35 U.S.C. 103(a) as being unpatentable over Neblock et al (Bioconjugate Chem. 3:126-131, 1992, IDS #4 ½) as applied to claims 27 and 30-31 above and further in view of Shalaby et al (J. Exp. Med 175:217-225, 1992) is maintained.

The response filed 11/17/03 and 10/14/03 have been carefully considered but is deemed not to be persuasive. The response states that Neblock et al contains a thioether-cross linked bispecific F(ab')₂ present at approximately 93%, not a composition as in Applicants' claim 30 comprising a correctly disulfide linked antibody fragment where as Applicants disclose on page 9 of the specification, all cysteine residues in the antibody are covalently associated as disulfide bonds and these disulfide associations correspond to the disulfide associations of the native immunoglobulin (see page 6 of response). In response to this argument, the same response as above for the 102 rejection is applied.

Conclusion

10. No claim is allowed.

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, Ph.D, whose telephone number is (703) 306-5879. The examiner can normally be reached on Monday through Friday from 7:00 am to 4:30 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

13. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the

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Art Unit: 1642

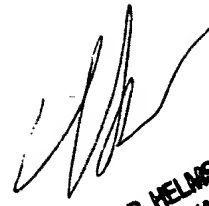
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Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 308-4242.

Respectfully,

Larry R. Helms Ph.D.

703-306-5879



LARRY R. HELMS, PH.D.
PRIMARY EXAMINER